



Session #4: Testing Paradigms

Moderator: Erica Takai, FDA

Potential Tests for Consideration

Pitting/Crevice Corrosion
ASTM F2129

Galvanic Corrosion

Open Circuit Potential

Surface Characterization

Nickel Leach
(in vitro)

Nickel Leach
(in vivo)

Animal Studies

Fretting/Fatigue

Other?

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Corrosion testing:

- Currently, ASTM F2129 is generally used to assess pitting/crevice corrosion
 - Is F2129 a sufficient assessment of clinically relevant corrosion?
 - If not,
 - Is there a way to modify F2129 to be more clinically relevant (e.g. acceptance criteria)
 - Are there other assessments in lieu of or in addition to F2129 to assess clinically relevant corrosion?

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Corrosion testing:

- Under what conditions should galvanic corrosion testing be considered?
 - If ASTM F2129 results are “good” should galvanic corrosion testing still be performed?

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Surface characterization:

- Is surface characterization testing needed in general?
- If not, when should it be considered? (e.g. “poor” ASTM F2129 test results, fractures)
- Can surface characterization testing be used to obviate the need for other tests, and if so which ones and under what conditions?
- If surface properties change, what other tests should be repeated?

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Nickel leach

- Under what conditions should in vitro nickel leach testing be considered (e.g. “poor” ASTM F2129 test results, fractures, “poor” surface characteristics)?
 - Should open circuit potential be performed in tandem with in vitro nickel leach testing?
- Under what conditions should in vivo nickel leach testing be considered?



Next Steps: Post Workshop

- Transcript and FDA slides to be posted on workshop website
- FDA Guidance planned
- White paper on workshop highlights and de-identified compiled homework (if acceptable to HW respondents)

Thank You for Participating!